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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/377,675 | 08/19/1999 | BRADLEY B. OLWIN | 2848-32 | 8188 |

22442 7590 12/31/2002

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EXAMINER

CHERNYSHEV, OLGA N

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1646

DATE MAILED: 12/31/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/377,675

Applicant(s)

OLWIN ET AL.

Examiner

Olga N. Chernyshev

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 19-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: .

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DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group II in Paper No. 11 is acknowledged. The traversal is on the ground(s) that "search for invention of Group I should also include the subject matter of Group II". This is not found persuasive because inventions of Groups I and II are directed to different chimeric FGFs that are represented by separate molecular embodiments. FGF-1 and FGF-2 are different growth factors, they have a separate status in the art and, therefore, will require non-coextensive divergent subject matter search. Furthermore, FGF-2 of the chimeric FGFs of the instant invention is represented by two species of human and bovine FGF-2, which required sequence search of at least four sequences. Examination of additional sequences related to a different FGF is clearly burdensome for both the Examiner and USPTO resources.

In response to Applicant's referral to *In re Ochiai* to support the traversal of restriction requirement, it is acknowledged that the method claims commensurate in scope with any allowed product claims will be rejoined upon allowance of the product claims.

The requirement is still deemed proper and is therefore made FINAL.

Claims 19-42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in Paper No. 11.

Claims 1-18, in so far as they are directed to chimeric FGF-2 are under examination in the instant office action.

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Oath/Declaration

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

Drawings

3. It is noted that figures of the instant specification contain bar graphs that are difficult to understand due to the poor quality of copies, perhaps. For example, Fig. 2 contains a legend that provides description of two bar graphs of the same color and pattern, so that it is impossible to distinguish which graph relates to "One Cell" or to "Two (+) Cells" data. Revision of the presentation of the figures is advised.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 4 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a chimeric fibroblast growth factor (FGF), which is encoded by a nucleic acid molecule that hybridizes to a complement of a nucleic acid molecule encoding FGF-2 protein, does not reasonably provide enablement for the chimeric fibroblast growth factor (FGF), which

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is encoded by a nucleic acid molecule that hybridizes to a nucleic acid molecule encoding FGF-2 protein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Claim 4 is directed to the chimeric fibroblast growth factor (FGF), which is encoded by a nucleic acid molecule that hybridizes to a nucleic acid molecule encoding FGF-2 protein. The instant specification fails to provide any teachings on how to produce a protein, which is encoded by a nucleic acid molecule that hybridizes to the nucleic acid molecule encoding that same protein. The prior art does not describe any protocol on how to produce the product, as claimed. Therefore, it would require undue experimentation and making a substantial inventive contribution for one skilled in the art before being able to successfully practice Applicant invention, as currently claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 1 is indefinite for recitation "said chimeric fibroblast growth factor (FGF) is characterized by fibroblast growth factor (FGF) biological activity in the absence of heparan sulfate". It is not clear if in the absence of heparan the chimeric FGF has the activity of FGF or it has the activity that FGF displays in the absence of heparan. Clarification is required.

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7. Claim 2 is vague and indefinite for recitation of "said FGF". Recitation of "said chimeric FGF" would obviate this ground of rejection.
8. Claim 4 is indefinite and ambiguous for recitation of hybridization "under stringent conditions". Without providing a precise set of hybridization conditions, in the claim or the specification, the metes and bounds of the claimed isolated nucleic acid molecule cannot be defined.
9. Claims 3 and 5-18 are indefinite for being dependent from indefinite claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1, 3, 5-7 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Fiddes et al. (US Patent 5, 604,293, reference 1 of IDS of Paper NO. 4).

Claims 1, 3, 5-7 are directed to a chimeric fibroblast growth factor (FGF) comprising an FGF-2 and a penetratin peptide, wherein said penetratin peptide transports said chimeric FGF-2 across a lipid bilayer of a cell. Fiddes et al. describe a construct of FGF-2 and a signal sequence, column 10, lines 15-25. Because the instant claims encompass transport of the claimed chimeras across a lipid bilayer regardless of the direction, inside or outside the cell, the claimed subject matter is fully anticipated by the document of Fiddes et al.

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Double Patenting

11. Applicant is advised that should claim 5 be found allowable, claim 7 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Conclusion

12. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 782-9306 for regular communications and (703) 782-9307 for After Final communications.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)0. NOTE: If Applicant *does* submit a paper by fax, the original

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signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D.
December 23, 2002

OC


JOHN ULM
PRIMARY EXAMINER
GROUP 1800